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SURGICRAFT

JUN 13 2008

510 (k) Summary

A	510(k) Owner	Surgicraft Limited 16 The Oaks Clews Road Redditch, Worchester England B98 7ST
	Contact	Donald W. Guthner Orgenix, LLC 111 Hill Road Douglassville, PA 19518 (888) ORGENIX (484) 363-5879 (FAX) dg@orgenix.com
	Preparation Date	February 18, 2008
B	Trade Name	Surgicraft Screw Fixation System
	Common Name	Fixation Bone Screw and Washer
	Classification Name	21 CFR 888.3040 MBI Smooth or threaded metallic bone fixation fastener Class II
C	Predicate Device(s)	The subject device is substantially equivalent to similar previously cleared devices. Substantial equivalence for the *Surgicraft Screw Fixation System* is based on its similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices cleared under the following submissions: ♦ K043185 – Stryker 3.5mm Cortex Screws ♦ K071157 - Stryker Titanium Intraline Anchor ♦ K973775 - Biomet Harpoon Suture Anchors ♦ K012572 – Biomet Soft Tissue Screws and Washers

D	Device Description	The *Surgicraft Screw Fixation System* is manufactured from stainless steel and titanium. The self-tapping 3.5 mm screws are available in lengths from 20- 40 mm in 1 mm increments. The washers have an inner hole diameter of 4.2 mm and an outer diameter ranging from 7 to 9 mm in 1 mm increments.
E	Intended Use	The *Surgicraft Screw Fixation System* is a single-use, soft tissue anchor which will be used to secure soft tissue to bone during reconstructive surgery. The anchor is intended for use in such procedures as: **Shoulder:** * Rotator Cuff Repair * Bankart Repair * SLAP Lesion Repair * Acromio-Clavicular Separation Repair * Capsular Shift/Capsulolabral Reconstruction * Biceps Tenodesis * Deltoid Repair. **Elbow. Wrist.** Hand: * Scapholunate Ligament Reconstruction * Ulnar Collateral Ligament Reconstruction * Radial Collateral Ligament Reconstruction * Biceps Tendon Reattachment. **Foot and Ankle:** * Medial Instability Repair/Reconstruction * Lateral Instability Repair/Reconstruction * Achilles Tendon Repair/Reconstruction * Midfoot Reconstruction * Hallux Valgus Reconstruction. **Knee:** * Extra Capsular Repairs o Medial Collateral Ligament o Lateral Collateral Ligament o Posterior Oblique Ligament * Illiotibial Band Tenodesis * Patellar Tendon Repair. **Pelvis:** *Bladder Neck Suspension Procedures.
F	Technological Characteristics	As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States. Engineering drawings, labeling, and mechanical testing have

		demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device.
G	Non-Clinical Testing	The *Surgicraft Screw Fixation System* was tested as follows: • Mechanical Testing ASTM – F543 - Standard Specification and Test Methods for Metallic Medical Bone Screws
H	Clinical Testing	Not applicable to this device
I	Conclusions	Based on the 510(k) Summary and the information provided herein, we conclude that the *Surgicraft Screw Fixation System* is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.
J	Additional Information	No additional information

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2008

Surgicraft, Ltd.
% Mr. Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, Pennsylvania 19518

Re: K080447
Trade/Device Name: Surgicraft Screw Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: May 13, 2008
Received: May 14, 2008

Dear Mr. Guthner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devicesand
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080447

Device Name: Surgicraft Screw Fixation System

Indications for Use:

The *Surgicraft Screw Fixation System* and is a single-use, soft tissue anchor which will be used to secure soft tissue to bone during reconstructive surgery. The anchor is intended for use in such procedures as:

Shoulder:
* Rotator Cuff Repair
* Bankart Repair
* SLAP Lesion Repair
* Acromio-Clavicular Separation Repair
* Capsular Shift/Capsulolabral Reconstruction
* Biceps Tenodesis
* Deltoid Repair.

Foot and Ankle:
* Medial Instability Repair/Reconstruction
* Lateral Instability Repair/Reconstruction
* Achilles Tendon Repair/Reconstruction
* Midfoot Reconstruction
* Hallux Valgus Reconstruction.

Elbow. Wrist. Hand:
* Scapholunate Ligament Reconstruction
* Ulnar Collateral Ligament Reconstruction
* Radial Collateral Ligament Reconstruction
* Biceps Tendon Reattachment.

Knee:
* Extra Capsular Repairs
  - -o Medial Collateral Ligament
  - Lateral Collateral Ligament
  - Posterior Oblique Ligament
* Illiotibial Band Tenodesis
* Patellar Tendon Repair.

Pelvis:
*Bladder Neck Suspension Procedures. Single patient use only

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for mkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080447